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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,158	03/28/2001	Kimberly O. Cameron	PC8835ETMC	4965

7590 03/30/2009

Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/820,158	CAMERON ET AL.	
	Examiner	Art Unit	
	ALTON N. PRYOR	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 5-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 5-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's arguments filed 1/9/09 have been fully considered but they are not persuasive. Previous rejections/issues not addressed below are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification while providing enablement for the treatment of treating breast cancer, does not reasonably provide enablement for preventing breast cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the

Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. Applicant is purporting to prevent breast cancer. However, only treatment of breast cancer is provided.

2) Nature of the invention

The nature of the invention is directed to treatment of breast cancer comprising administering estrogen type compounds to a mammal.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of cancer research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess a Ph.D. or M.D. in a scientific discipline such as medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

Cancer research is difficult. State of the art cancer research comprises laborious time-consuming and costly experimental methods comprising functional and non-functional assays representing both in vitro and in vivo experiments. (Zips et al. In vivo 2005, 19, 1-8). The art teaches that there is no known prevention for breast cancer using instant estrogen type compounds (Lednicer et al, J. Med. Chem., 12 881, 1969).

5) Level or degree of predictability, or a lack thereof, in the art

Sikora teaches that the common solid tumors such as breast, lung, prostate and colorectal cancer are only partially responsive to drug therapy (Page 549, right column; Sikora Current Science 2001, 81(5), 549-554). Thus, not all anti-cancer drugs are effective at treating all tumors. The art teaches that not all tumor cell lines show the same magnitude of response to anticancer agents (page 2 right column

and throughout; Zips et al. In vivo 2005, 19, 1-8). Furthermore, Zips et al. teach; "Many of the new anticancer drugs reduce tumor growth but do not eradicate the tumor." (Page 5, lower right column).

6) Amount of guidance or direction provided by the inventor

Applicants' examples show the effect of estrogen like compounds on the control and prevention of endometriosis, prostate weight, cholesterol levels and obesity. See pages 19-24 of the specification.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to a method of preventing breast cancer using instant estrogen type compounds. No further evidence has been provided.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct time-consuming and costly experimental methods comprising functional and non-functional assays representing both in vitro and in vivo experiments to determine if this invention works. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to determine if the method does indeed prevent breast cancer.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Response to Applicants' arguments

Applicant argues "the prevention of breast cancer is a credible utility that is clear, definite and understood by one skilled in the art. Applicants submit that one skilled in the art understands that the reduction in incidence of breast cancer is prevention of breast cancer.

To illustrate the knowledge of those skilled in the art with respect to the prevention of breast cancer, applicants are submitting herewith the FDA approved label for tamoxifen citrate and three documents printed from the web site of the National Cancer Institute.

The compound tamoxifen citrate (sold as Nolvadex® by AstraZeneca) is presently approved by the FDA and is indicated for "Reduction in Breast Cancer Incidence in High Risk Women." The reduction in incidence of breast cancer indication was approved on the basis of "The Breast Cancer Prevention Trial", "The Italian Tamoxifen Prevention trial" and the "Royal Marsden Trial" which are described at pages 8 through 14 of the Nolvadex® label submitted herewith. These trials were conducted in order to determine whether administration of tamoxifen would prevent breast cancer in women at high risk of developing the disease. After a median period of 4.2 years, tamoxifen was shown to reduce the incidence of breast cancer (i.e. prevent breast cancer) by 44% when compared to placebo in "The Breast Cancer Prevention Trial" (see the Nolvadex® label at page 10, lines 10-16)."

The Examiner argues that none of the literature provided by the applicants supports or demonstrates that instant estrogen like compounds are effective in preventing or reducing the incidence of breast cancer. The Applicants provide beast cancer preventive data for Lasofoxifene in paper filed 8/7/08 which is a species in the claimed genus. The Applicants also explain in the paper filed 8/7/08 that Lasofoxifene reduces the risk of or the incidence of breast cancer. The Applicants explains that the prevention of breast cancer is a well known phrase in the breast cancer art and the phrase is understood to mean reduce the risk of or the incidence of breast cancer. The Applicants provide literature references ("NOLVADEX" and "Cancer Facts" – from "NATIONAL CANCER INSTITUTE") which supports that the term "prevention" in the breast cancer art means to reduce the risk of or the incidence of breast cancer. The Examiner points out that the literature references clearly explains that the prevention of breast cancer means to reduce the risk of or the incidence of breast cancer. On the other hand, the instant specification does not make it clear that the prevention of breast cancer means to reduce of or incidence of breast cancer. Therefore, although paper filed 8/7/08 reveals that Lasofoxifene prevents breast cancer by reducing the risk of or the incidence of breast cancer, the specification does not appear to define the scope of preventing breast cancer.

Applicants argue that "prevention" is defined in the Webster Dictionary as being "the act of preventing or hindering and that preventing means to keep from happening or existing." Applicants state, ""prevention of breast cancer" thus means that breast cancer is kept from happening or existing which therefore means that the risk of or

incidence of breast cancer is reduced." Applicants further argue that in their August 7, 2008 response it is stated that the compounds of Formula I in the instant claims can be used to reduce the incidence, and thus prevent breast cancer based on clinical data. The Examiner realizes that the arguments provided in the response of 1/9/09 center around the use of the phrase "preventing breast cancer". The Examiner agrees that in the Applicants' response filed August 7, 2008 states that "preventing breast cancer" means reducing the incidence of breast cancer. However, the Examiner argues that nowhere in Applicants' specification is it defined that "preventing breast cancer" means to "reduce the incidence of breast cancer". The Examiner also acknowledges the Webster's dictionary definition of "prevention" provided by the Applicants. However, the Examiner reiterates that Applicants provides no definition of prevention in the specification. The Examiner notices that the definition of prevention covers, "keep from happening or existing". The Examiner is requesting the Applicants to show how instant compounds keep breast cancer from happening or existing. Thus, the state of the art, including Zips et al., is drawn to the treatment of breast cancer after occurrence.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON N. PRYOR whose telephone number is (571)272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/
Primary Examiner, Art Unit 1616